UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/954,789	09/12/2001	Charlie Ricci	018413-378	8809

38706 7590 02/27/2007

FOLEY & LARDNER LLP
1530 PAGE MILL ROAD
PALO ALTO, CA 94304

EXAMINER	
WANG, SHENGJUN	
ART UNIT	**PAPER NUMBER**
1617	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/27/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	09/954,789	RICCI ET AL.	
	Examiner	Art Unit	
	Shengjun Wang	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 January 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16,20-31 and 33-44* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16,20-31 and 33-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

The amendment filed January 24, 2007 have been entered.

The Board of Patent Appeals and Interferences has reversed the rejections set forth in the final rejections mailed April 21, 2004 and remanded the application to the examiner for further consideration of the prior art regarding "stent graft." On further consideration, the prosecution is herein reopened in favor of following action.

Claim Rejections 35 U.S.C. 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16, 20-31, 33-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCrory (US 5,951,599, of record), in view of Evens (5,695,480,of record and 5,702,361) and, IDS and in further view of applicants' admission on pages 3 and 18, Krysl and Holzenbein et al (IDS).

The instant claims are directed to kits comprising a fluid composition that forms a coherent mass in the presence of blood comprising a biocompatible solvent and a biocompatible polymer, a catheter suitable for delivering the fluid composition, a catheter suitable for delivering an endovascular prosthesis to the aneurysm, and an endovascular prosthesis comprising a stent-graft. As to the definition of "stent-graft", absent particular definition in the

specification, the term is given the broadest interpretation: a stent with means to graft to the tissue.

McCrory teaches occlusive systems including a stent for deployment in the parent vessel, a catheter for insertion of the device, a liquid polymeric embolizing composition to seal aneurysm sac and a microcatheter to deliver the embolizing composition (see abstract, col. 3, lines 60-col 4, lines 24; col. 5, lines 25-58; col. 6, lines15-60 and figures 6A-B; col. 8, line50-col 9, line 20; col. 12, lines 13-25). The stent of McCrory is an endovascular prosthesis. The composition of McCrory meets the element (a) of the instant claims because a liquid embolizing compositions comprises a biocompatible polymer and solvent.

McCrory does not teach expressly that the stent employed therein is a stent-graft, or a particular kit as herein claimed.

However, Evans shows assembling a kit for vascular repair procedure comprising an embolic polymeric composition, which solidifies in vivo. Evans also teaches a prosthetic device such as a metal coil with different size catheters for delivering the composition and arresting the blood flow during the procedure (see abstract, col. 4, lines 2-47; col. 10, lines 31-41; col. 11, lines 52-67; col. 13, lines 1-43, US 5,695,480). Evans also disclosed that other components, such as the water –insoluble contrast agents and water-soluble contrast agents, col. 8, lines 50 in the claimed kit, are required. See, particularly, col. 4, lines 2-9, col. 8, lines 50-53 (US 5,695,480). Evans further discloses that the contrast agents herein are well-know in the art See, col. 6, lines 26-37 (US 5,702,361). Furthermore, as applicants admitted, and as evidenced by Krysl et al. and Holzenbein et al. stent graft was well-known in the art for repairing Abdominal Aortic aneurysm (AAA) at the time the claimed invention was made. Particularly, Appellants' specification, page

18, lines 7-14, states, "[s]uitable endovascular prostheses for endovascular repair of abdominal aortic aneurysms are well known in the art and are described, for example, by Beebe[]. Such prostheses, by themselves, do not form part of this invention." In addition, the specification, page 3, references the November 1998 publication by Parodi, "Endovascular AAA Stent Grafts: Training and Proper Patient Selection." Krysl et al. provide evidence that stent graft was used for treatment of AAA in 1995. See the entire document. Holzenbein et al. also revealed that stent graft was used for treatment of AAA and commercial products were available. See, particularly, page 208. Further, Krysl and Holzenbein et al. both teaches that endoleaks arise from a variety of reasons have been noted. See, page 659 of Krysl and table 2 at page 211 of Holzenbein et al.

Therefore, it would have been prima facie obvious at the time the claimed invention was made to combine two compositions each of which is taught by prior art to be useful for same purpose in order to form third composition that is to be used for very same purpose; idea of combining them flows logically from their having been individually taught in prior art; thus, claims that require no more than mixing together of conventional elements used in the art for the same purpose set forth prima facie obvious subject matter. In re Kerkhoven, 205 USPQ 1069 (CCPA) 1980. In the instant case, all elements of the instant claims are taught in the art. Accordingly, it would have been obvious at the time of invention to add a stent-graft well known in the art to McCrory's system and assemble a kit to facilitate convenience during a vascular repair procedure as taught by Evens. It is particularly noted that use stent graft for treatment of AAA is well-known in the art (See, applicant's admission at pages 3 and 18, Krysl and Holzenbein et al). The limitation of endoleaks "arising from incomplete sealing at the interface of the arotic wall and the end of the prosthesis or from defects within the endovascular

prosthesis" is not seen to distinguish the claims from prior art as such leakages have been well recognized in the art.

Response to Applicant's Arguments

Applicants' amendemnts and remarks submitted January 24, 2007 have been fully considered, but are not persuasive.

Applicants state on the record that focus placed on the functional equivalency between stents and stent grafts is not relevant to the patentability of the pending claims. Applicants assert that the patentability of claimed invention reside on the fact that the claimed invention are directed to kit comprising a *defective stent graft*. The arguments are not persuasive, particularly in view of Krysl and Holzenbein et al, which showed that endoleaks after implant stent graft is common. Further, as shown by Holzenbein et al. Holzenbein et al. discloses that endoleaks may arise from a variety of reasons, such as anatomic reasons, graft misplacement. Therefore, there is a uniform design of stent graft that fit all the AAA as the shape of the pathogenic site may various. Therefore, essentially no of the commercial stent graft is perfect to fit all AAA patients, and may be considered "defective".

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang whose telephone number is (571) 272-0632. The examiner can normally be reached on Monday to Friday from 7:00 am to 3:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Shengjun Wang
Primary Examiner
Art Unit 1617

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER